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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,377	06/22/2007	Michael Dauner	PAT 62246W-2	3317

42534 7590 11/04/2008
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EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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11/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,377	Applicant(s) DAUNER ET AL	
	Examiner HERBERT J. LILLING	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08-25-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Receipt is acknowledged of an election response filed October 15, 2008.
2. Claims 1-15 remain pending in this application.
3. Applicant has elected with traverse Group I, claims 1-15, and canceled claims 16-21. In addition, Applicant has indicated that claims 1-11 are drawn to the elected species and claims 12-14 have been withdrawn as directed to non-elected species.

If the elected species are found to be allowable,

The restriction and election of species are proper as submitted.

The restriction and election of species have been made final.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in view of an alleged formula (no known evidence in the field that this apparently new formula has any patentable reliability in the field of working with biological cells based on the incomplete formula. The formula lacks the appropriate

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units for each of the symbols to make an appropriate search as to T_K and T_M which are lacking and the symbol t_h is not defined whereas "WE" has the units of " $^{\circ}\text{K. sec}$ ".

Applicant is requested clearly indicate the patentability subject matter since the formula apparently does not express any advancement in the art as well as a showing that the generic formula is useful for any biological cell.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1, line 4, recites the limitation "wherein the "thermal equivalent" (WE)," since there is no antecedent basis for this in lines 1-3 of Claim 1. There is insufficient antecedent basis for this limitation in the claim as well as in claims 2-11 based on this limitation.

b) Vague and indefinite as to the symbols for the claimed formula in claim 1 which are lacking in the formula expression. In addition, the range is in degrees Kelvin as well as the symbol for the time appears to be in hours. Claims 2 and 5 are in degrees Centigrade whereas the formula is in degrees Kelvin which are presumed to be correct but confusing in view of the lack of suitable definition in formula of claim 1.

c) Claims 7 and 8 lack suitable full definition of the value of WE which lacks the time unit(s).

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d) Claims 9 and 10 are drawn to a "temperature-controlled segment of a capillary" based on formula of claim 1 which does not contain any mathematical adjustments for the volume as noted by claim 10.

e) Claim 15 lacks antecedent basis for "wherein the component material is an intracellular metabolite,".

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al, US 6,197,553 for the grounds submitted on the record by the Examiner, see the International Search Report, whereby the Examiner indicated column 3, lines 38-53; column 5, lines 10-27; claim 1; figure 1 and examples 1 and 2. The reference is considered to be within the scope of the claimed formula which only requires the two temperatures and time for the conditioning which are met as indicated above and if there are any differences, Applicant is required to show patentable differences over the reference.

7. **No claim is allowed.**

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HERBERT J. LILLING whose telephone number is 571-272-0918. The examiner can normally be reached on WORK AT HOME MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL

(571) 272-0918

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October 25, 2008

/HERBERT J LILLING/
Primary Examiner Art Unit 1657